K060007

Attachment 4

MAR 2 3 2006

510(k) Summary Of Safety and Effectiveness

I. General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 § 807.92

Establishment:

- Address: BD Medical – Pharmaceutical Systems
  1 Becton Drive
  Franklin Lakes, NJ 07417-1885
- Registration Number: 2243072
- Contact Person: James W. Haynes
  Senior Regulatory Affairs Specialist
  Telephone No.: 201-847-4298
  Fax No.: 201-847-7040
- Date of Summary: December 28, 2005

Device

- Trade Name: BD AutoShield™ Pen Needle
- Classification Name: Single Lumen Hypodermic Needle
- Classification: Class II
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

II. Safety and Effectiveness Information Supporting Substantial Equivalence

- Device Description

The BD AutoShield™ Pen Needle is designed for use with pen injectors for subcutaneous injection of a desired dose of drugs approved for delivery using a pen needle. The BD AutoShield™ Pen Needles are offered in various gauges sizes (29G, 30G, and 31G) and lengths (5mm, 8mm, and 12.7mm). The BD AutoShield™ Pen Needle is sterile (gamma irradiation sterilization), non-toxic, and non-pyrogenic. It is a disposable, single use device.
Additionally, the BD AutoShield™ Pen Needle is designed to reduce occurrence of accidental needle sticks from the patient end of the needle by providing a shield that locks over the needle after use. Prior to injection, the user will attach the AutoShield™ Pen Needle to the pen. The shield of

AutoShield™ Pen Needle will hide the needle from the user prior to use. As the user proceeds with inserting the needle into the skin at a 90° angle, the shield will retract. After the injection is completed and needle is removed from the skin, the shield will automatically extend to cover the needle and lock in place. The AutoShield™ Pen Needle should be removed from the pen and discarded.

- Intended Use

The BD AutoShield™ Pen Needle is intended for use with pen injector devices for the injection of drugs, including insulin and exinatide.

Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.

- Synopsis of Performance Study Results

Bench testing and simulated clinical testing was performed to confirm the device's safety and efficacy. Clinical testing was performed to evaluate the function of the of the safety feature in a simulated clinical environment utilizing both professional health care workers and non-clinician pen users.
Based on these performance testing results, the BD AutoShield™ Pen Needle is safe and effective when used as intended.

III. Predicate Device Summary Table

- Substantial Equivalence

Based on comparison of the device features, materials, intended use and performance, the BD AutoShield™ Pen Needle was shown to be substantially equivalent to the commercially available predicate device indicated in the table below. The predicate device, K number, and clearance date are also identified in the table below.

Manufacturer	Predicate Device	K-Number	Clearance Date
Becton Dickinson	BD Pen Needle	K051889	September 13, 2005

James W. Haynes
Senior Regulatory Affairs Specialist
Becton Dickinson Medical – Pharmaceutical Systems
Becton Dickinson and Company

12/30/05
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2006

Mr. James W. Haynes
Senior Regulatory Affairs Specialist
BD Medical-Pharmaceutical Systems
Becton, Dickinson and Company
1 Becton Drive (MC 440)
Franklin Lakes, New Jersey 07417

Re: K060007
Trade/Device Name: BD AutoShield™ Pen Needle
Regulation Number: 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: II
Product Code: FMI
Dated: February 8, 2006
Received: February 10, 2006

Dear Mr. Haynes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

510(K) NUMBER (IF KNOWN): K060007

DEVICE NAME: BD AutoShield™ Pen Needle

INDICATIONS FOR USE:

The BD AutoShield™ Pen Needle is intended for use with pen injector devices for the injection of drugs, including insulin and exinatide.

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PRESCRIPTION USE _____ OR OVER-THE-COUNTER USE X
(PER 21 CFR § 801.109) (OPTIONAL FORMAT 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Clinical Pharmacology, General Hospital
Ophthalmic and Dental Devices

K060007